IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TENNESSEE
WESTERN DIVISION

GARY BRYAN BRACKIN, individually and in his capacity as Surviving Spouse of PAMELA W. BRACKIN, Deceased,	
Plaintiff,	**Case No. 2:17-cv-2101**
v.	
MEDTRONIC, INC., et. al,	
Defendants.	

DEFENDANTS MEDTRONIC, INC.'S AND MEDTRONIC MINIMED, INC.'S MEMORANDUM OF LAW IN SUPPORT OF MOTION TO EXCLUDE OPINIONS AND TESTIMONY OF WILLIAM J. VIGILANTE, JR., PH.D, CPE

Defendants Medtronic, Inc. and Medtronic MiniMed, Inc. (collectively, "Medtronic Defendants"), by and through their undersigned counsel, submit this Memorandum of Law In Support of Motion to Exclude the Opinions and Testimony of William J. Vigilante, Jr., Ph.D, CPE, in its entirety, pursuant to Federal Rules of Civil Procedure 702 and 703 and associated jurisprudence, showing the Court as follows:[1]

I. INTRODUCTION

Plaintiff identified William J. Vigilante, Jr., Ph.D, CPE ("Dr. Vigilante") as a human

[1] Dr. Vigilante has not been deposed in this matter, but the Medtronic Defendants cite to his testimony in numerous other cases to demonstrate his lack of qualifications to opine on the topics at issue here, including his deposition testimony in the *Dennert v. Medtronic* case where he sought to opine on similar topics. The only date provided by Plaintiff's counsel for the deposition of Dr. Vigilante was September 14, 2018 – the last day of discovery and the date the *Daubert* motions are due. The Medtronic Defendants reserve the right to supplement this Motion based on testimony provided at his deposition.

factors and warnings expert. According to the report provided by Plaintiff, Dr. Vigilante intends to offer opinions about (1) the adequacy of instructions and warnings for the device at issue; (2) the adequacy of the Medtronic Defendants' human factors analysis in designing the device at issue; and (3) medical causation for Pamela Brackin's injury and death. For the reasons set forth below, Dr. Vigilante is not qualified to provide expert opinions related to FDA-regulated medical devices or any aspect of medical causation. Indeed, Dr. Vigilante has zero experience or qualifications with respect to medical device labeling or warnings – the precise area addressed in his expert report. Moreover, the whole of his causation testimony should be excluded because it is based on unsubstantiated assumptions and he has not used a reliable methodology to arrive at his opinions. Accordingly, all of Dr. Vigilante's proposed testimony is inadmissible under the Federal Rules, and the Court should exclude his written report and proposed testimony in its entirety.

II. FACTUAL BACKGROUND[2]

A. REGULATORY APPROVAL OF THE PARADIGM® MMT-523 INSULIN PUMP AND 510(K) CLEARANCE OF THE RESERVOIR AND INFUSION SET

The Medtronic MiniMed Paradigm® MMT-523 insulin pump ("Pump") is a Class III medical device. Under this regulatory scheme, Class III medical devices, such as the Pump, are subject to a lengthy and rigorous premarket approval process (PMA), during which the FDA closely and rigorously scrutinizes PMA applications to weigh "'any probable benefit to health from the use of the device against any probable risk of injury or illness from such use.'" *Riegel v.*

[2] The Medtronic Defendants' Motion for Summary Judgment is being filed contemporaneously herewith. In the interest of brevity, and in addition to the facts included herein, the Medtronic Defendants refer the Court to their Statement of Uncontroverted Material Facts in Support of Motion for Summary Judgment and incorporate those facts by reference as if fully set forth herein.

Medtronic, Inc., 552 U.S. 312, 318 (2008) (quoting 21 U.S.C. § 360c(a)(2)(C)). The content of the labeling, including all warnings, representations, and other information therein or omitted therefrom, are all specified by the FDA through its regulations and its line-by-line review during the PMA process. *See id.* The Pump at issue in this action was submitted as a supplement to the original PMA for the Paradigm® Real Time System and was approved by the FDA on March 10, 2010. The reservoir and infusion set are Class II devices, and thus, along with the accompanying labeling for those components, were cleared by the FDA through the FDA's 510(k) process.

Given the FDA's role in approving and regulating the labeling and warnings of the Pump, the reservoir, and the infusion set, expertise with respect to regulatory and FDA oversight of the medical device industry is a prerequisite to opining as to the adequacy of the warnings and labeling of the Pump, the reservoir, and the infusion set.

B. DR. VIGILANTE'S EXPERT REPORT[3]

1. DR. VIGILANTE'S PURPORTED EXPERT OPINIONS AND ANALYSIS

Dr. Vigilante's expert report, dated July 31, 2018, begins with an Introduction that largely summarizes the allegations in Plaintiff's Complaint. (Report of William Vigilante, Ph.D, dated July 31, 2018, attached as Exhibit A, at 2 ("Vigilante Report")). Notably, in recounting the events, the Introduction speculatively and without support states, "At some point the system malfunctioned causing an unintended and unknown over-infusion of insulin into Pamela's body." (*Id.*). Dr. Vigilante wrote the purpose of his investigation was to determine if:

> (1) "Medtronic's failure to conduct an adequate human factors analysis of its products was improper in a manner which caused or contributed to Pamela Brackin's injury and death."

[3] A copy of Dr. Vigilante's expert report ("Report"), as provided by Plaintiff's counsel, is attached hereto as **Exhibit A**.

(2) "Medtronic provided adequate instructions and warning with its Paradigm reservoir and infusion set regarding the hazard associated with the potential blockage of the P-cap connector vent."

(3) "Medtronic's failure to provide adequate instruction and warning regarding the hazard associated with the potential blockage of its P-cap connector vent was improper in a manner which caused or contributed to Pamela Brackin's injury and death."

(*Id.*). He then referenced his curriculum vitae ("CV") outlining his qualifications. (*Id.* at 3).

Dr. Vigilante's report lists the materials that he had available during his review. (Vigilante Report at 3). The documents related to the Pump include the Medtronic Getting Started Guide, but Dr. Vigilante did not review the full set of instructions that came with the Pump. (*See id.*). He notes that the Pump comes with a 243-page user guide, but his review consisted only of the Medtronic Getting Started Guide and the Instructions for Use ("IFU") for the reservoir and infusion set. (*Id.* at 5). He describes the incident largely by referencing Plaintiff's Complaint and deposition. (*Id.* at 5-7). Critically, he did not review any of the regulatory submissions, approvals, or clearances of the Pump, reservoir, or infusion set and their associated warnings and labeling. Nor did he conduct any experimentation or testing whatsoever to support his opinions.

Dr. Vigilante's "Analysis" section begins with the following statement: "The design of Medtronic's P-cap connector creates the potential hazard of unintended over or under delivery of insulin." (*Id.* at 7). Dr. Vigilante further concludes that "Medtronic failed to conduct a proper human factors analysis." (*Id.* at 9). Dr. Vigilante gives an overview of human factors analysis, then claims that the design of the Pump was "[c]ontrary to industry practices, guidelines, and standards," and that the Medtronic Defendants "failed to incorporate an adequate hazard analysis or human factors analysis into the design of its infusion set and reservoir." (*Id.* at 9-10).

Dr. Vigilante also faults "Usability Studies" conducted in the early 2000s for failing to "uncover the hazard inherent in the design of the P-cap and how foreseeable user misuse . . . could result in a failure of the connector cap and potentially result in an overdose." (*Id.* at 11-12).

2. DR. VIGILANTE'S EXPERIENCE IS UNRELATED TO MEDICAL DEVICES

Dr. Vigilante's CV[4] generally describes his experience with a broad range of products, most having to do with motor vehicles or premises liability actions, and nothing to do with medical devices. Dr. Vigilante's professional career began as an "Ergonomics Researcher" at the Center for Cumulative Trauma Disorders at Penn State University. (*Id.* at 3). He then worked for approximately seven years at International Business Machine Corporation ("IBM"), first as a "Human Factors Engineer Co-op," then as a "Human Factors Engineer," and finally as a "Human Factors/Usability Engineer Consultant." (*Id.* at 2-3). During his last three years at IBM his CV indicates he also worked as a "Forensic Scientist" for ARCCA, Inc., "[p]roviding background research, written reports, and testimony," as a "[c]onsultant for consumer product and safety hazard litigation." (*Id.* at 3). From 2003 to 2015, Dr. Vigilante worked at Fournier Robson, Inc., where he claims to have "[c]onsulted with manufacturers in the design, development, and/or assessment of product warnings and accompanied literature for consumer and commercial products," in addition to working as an Associate at Robson Forensic, Inc. (*Id.*). In 2015 Dr. Vigilante became a Principal at Vigilante Forensic. At both Vigilante Forensic and Robson Forensic, Inc. he primarily provides litigation consulting as a retained expert.

Dr. Vigilante's "Publications and Presentations" include topics completely unrelated to

[4] A copy of Dr. Vigilante's curriculum vitae (CV), as provided by Plaintiff's counsel, is attached hereto as **Exhibit B**.

the medical device at issue here. His publications and presentations deal with warnings and labeling of other products – not medical devices. He has also published and presented on boat accidents, the safety of riding bicycles at night, therapeutic responses in psychiatric inpatients, motorcycle helmet safety, web site survey results, programmable thermostats, and hunter's tree stands. Thus, nothing in his CV speaks at all to any education, training, or experience with medical device design or warnings and labeling. Nothing in his CV indicates any medical education, training, or experience.

ARGUMENT[5]

A. DAUBERT MOTION LEGAL STANDARD

The admissibility of expert opinion testimony is governed by Rule 702 of the Federal Rules of Evidence. *Daubert v. Merrell Dow Pharms., Inc*., 509 U.S. 579, 587 (1993); *United States v. Rios*, 830 F.3d 403, 412-13 (6th Cir. 2016); *Nelson v. Tenn. Gas Pipeline Co.*, 243 F.3d 244, 250 (6th Cir. 2001).[6] Rule 702 "provides the touchstone for expert testimony," *United States v. Cunningham*, 679 F.3d 355, 378 (6th Cir. 2012), pursuant to which trial judges serve as gatekeepers to its admission. *See Daubert*, 509 U.S. at 597; *Tamraz v. Lincoln Elec. Co.*, 620 F.3d 665, 668 (6th Cir. 2010). This gatekeeping function applies not only to testimony on "scientific" knowledge, but also to "technical" and "other specialized" knowledge. *Kumho Tire*

[5] The Medtronic Defendants reserve the right to move to exclude or limit this expert witness's opinions on grounds other than those set forth herein if those grounds become available subsequent to the filing of this Motion by virtue of the Court's rulings, any additional discovery that may take place in this case, or supplementation of this expert witness's disclosure or report.

[6] Where, as here, a federal district court exercises jurisdiction based on diversity, the Federal Rules of Evidence govern the admissibility of expert testimony. *See Bradley v. Ameristep, Inc.*, No. 1:12-CV-01196, 2014 WL 6474913, at *1 (W.D. Tenn. Apr. 14, 2014) ("Federal law governs admissibility of expert testimony in diversity cases."); *see also Back v. Nestle USA, Inc.*, 694 F.3d 571, 576-77 (6th Cir. 2012) ("In diversity cases, evidence admissibility is governed by the Federal Rules of Evidence.").

Co., v. Carmichael, 526 U.S. 137, 141, 147 (1999).

The U.S. Court of Appeals for the Sixth Circuit has summarized Rule 702 as requiring an expert witness to satisfy three prerequisites before his or her opinion is admissible: "First, the witness must be qualified by 'knowledge, skill, experience, training, or education.' Second, the testimony must be relevant, meaning that it 'will assist the trier of fact to understand the evidence or to determine a fact in issue.' Third, the testimony must be reliable." *In re Scrap Metal Antitrust Litig.*, 527 F.3d 517, 528-29 (6th Cir. 2008) (quoting Fed. R. Evid. 702 (2000) (amended 2011)); *accord Osborn v. Griffin*, 865 F.3d 417, 452 (6th Cir. 2017) (same); *Bradley v. Ameristep, Inc.*, 800 F.3d 205, 208 (6th Cir. 2015) (same); *ECIMOS, LLC v. Carrier Corp.*, No. 2:15-cv-2726-JPM-cgc, 2018 WL 3405421, at *2 (W.D. Tenn. May 20, 2018) (same).[7]

As to qualifications, "[t]he issue with regard to expert testimony is not the qualifications of a witness in the abstract, but whether those qualifications provide a foundation for a witness to answer a specific question." *Anglefix, LLC v. Wright Med. Tech., Inc.*, No. 13-CV-2407-JPM-TMP, 2017 WL 2973989, at *6 (W.D. Tenn. July 12, 2017) (quoting *Berry v. City of Detroit*, 25 F.3d 1342, 1351 (6th Cir. 1994)). "[A] witness is not a qualified expert simply because he self-

[7] Rule 702 provides in full:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:
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> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
>
> (b) the testimony is based on sufficient facts or data;
>
> (c) the testimony is the product of reliable principles and methods; and
>
> (d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702.

identifies as such," *Bradley*, 800 F.3d at 208-09, and "'[n]o matter how good' experts 'credentials' may be, they are 'not permitted to speculate.'" *Tamraz*, 620 F.3d at 671 (quoting *Goebel v. Denver & Rio Grande W. R.R. Co.*, 215 F.3d 1083, 1088 (10th Cir. 2000)). "Whether a proposed expert's experience is sufficient to qualify the expert to offer an opinion on a particular subject depends on the nature and extent of that experience." *Cunningham*, 679 F.3d at 379. "[I]f the subject of the testimony lies outside the witness's area of expertise," then "a court should exclude [the] proffered expert testimony." *Walter v. Auto-Owners Mut. Ins. Co.*, No. 3:15-CV-535-TAV-DCP, 2018 WL 3650284, at *11 (E.D. Tenn. Aug. 1, 2018) (citation omitted); *accord Ellipsis, Inc. v. The Color Works, Inc.*, 428 F. Supp. 2d 752, 758 (W.D. Tenn. 2006) (expert witness's "knowledge, skill, experience, training or education must be closely related to the subject matter of his testimony").

As to relevancy, this inquiry "is designed to ensure that 'there is a 'fit' between the testimony and the issue to be resolved by the trial.'" *Ellipsis, Inc.*, 428 F. Supp. 2d at 757 (quoting *Greenwell v. Boatwright*, 184 F.3d 492, 496 (6th Cir. 1999)). In other words, "there must be a connection between the scientific research or test being offered and the disputed factual issues in the case." *Anderson v. Dillard's, Inc.*, No. 2:04-CV-02548-BBD, 2008 WL 8940110, at *1 (W.D. Tenn. Oct. 8, 2008) (quoting *Pride v. BIC Corp.*, 218 F.3d 566, 578 (6th Cir. 2000)). "Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful." *Daubert*, 509 U.S. at 591 (citation omitted). Moreover, "[t]he relevancy of expert testimony … hinges on whether the subject matter presented is 'beyond the ken of the average juror.'" *Anglefix, LLC*, at 2017 WL 2973989, at *6 (quoting *Rios*, 830 F.3d at 412). "In short, expert testimony is not relevant … if the jurors are likely to understand the presented

material without expert testimony." *Id.*[8]

As to reliability, this inquiry "focuses on the 'methodology and principles' that form the basis for the testimony." *Ellipsis, Inc.*, 428 F. Supp. 2d at 757. "To be reliable, the opinion must not have 'too great an analytical gap' between the expert's conclusion, on the one hand, and the data that allegedly supports it, on the other." *Lozar v. Birds Eye Foods, Inc.*, 529 F. App'x 527, 530 (6th Cir. 2013) (quoting *Tamraz*, 620 F.3d at 675-76). "Red flags that caution against certifying an expert include reliance on anecdotal evidence, improper extrapolation, failure to consider other possible causes, lack of testing, and subjectivity," *Newell Rubbermaid, Inc. v. Raymond Corp.*, 676 F.3d 521, 527 (6th Cir. 2012), and "[a]n expert's testimony should be excluded when it 'amounts to mere guess or speculation.'" *Jack Tyler Eng'g Co. v. Colfax Corp.*, No. 10-02373, 2013 WL 1500510, at *2 (W.D. Tenn. Apr. 10, 2013) (quoting *United States v. L.E. Cooke Co.*, 991 F.2d 336, 342 (6th Cir. 1993)).[9] Although *Daubert* identified several factors that may bear on a judge's determination of the reliability of an expert's testimony, these factors are neither definitive nor exhaustive. *See Kumho Tire*, 526 U.S. at

[8] Even if expert testimony is logically relevant under Rule 702, it remains subject to exclusion for lack of legal relevancy under Rule 403. *See United States v. Semrau*, 693 F.3d 510, 523 (6th Cir. 2012) ("Rule 403 offers a basis for excluding evidence independent of Rule 702 and *Daubert*."). Therefore, the court may exclude relevant expert testimony under Rule 403 "if its probative value is substantially outweighed by a danger of one or more of the following: unfair prejudice, confusing the issues, misleading the jury, undue delay, wasting time, or needlessly presenting cumulative evidence." *United States v. LaVictor*, 848 F.3d 428, 444 (6th Cir. 2017*), cert. denied*, 137 S. Ct. 2231 (2017) (citation omitted).

[9] The Sixth Circuit also "has recognized for some time that expert testimony prepared solely for purposes of litigation, as opposed to testimony flowing naturally from an expert's line of scientific research or technical work, should be viewed with some caution." *Johnson v. Manitowoc Boom Trucks, Inc.*, 484 F.3d 426, 434 (6th Cir. 2007).

150.[10]

The proponent of expert testimony bears the burden of establishing its admissibility. *EEOC v. Kaplan Higher Educ. Corp.*, 748 F.3d 749, 752 (6th Cir. 2014); *W. Tenn. Chapter of Associated Builders & Contractors, Inc. v. City of Memphis*, 300 F. Supp. 2d 600, 602-03 (W.D. Tenn. 2004). Where, as here, the proponent fails to establish all of the prerequisites regarding the admissibility of expert testimony, its exclusion is within the trial court's discretion. *See Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 142 (1997).

B. DR. VIGILANTE IS NOT QUALIFIED TO OFFER ANY LABELING, WARNINGS, OR HUMAN FACTORS OPINIONS ABOUT FDA REGULATED MEDICAL DEVICES OR ANY ENGINEERING OR DESIGN OPINIONS ABOUT FDA REGULATED MEDICAL DEVICES

Dr. Vigilante seeks to testify regarding Dr. Vigilante's general background evaluating warnings as a human factors consultant does not qualify him to offer expert opinions related to the warnings, labeling and instructions of a medical device like the Pump, Infusion Set, or Reservoir. Expert evaluation and criticism of the warnings and labeling of the Pump, the Infusion Set, or Reservoir requires expertise in FDA laws, regulations, and other regulatory information related to medical devices. Dr. Vigilante lacks any professional knowledge or experience related to medical devices, particularly medical device labeling and warnings, and the FDA regulations, laws, and other information governing medical devices.

Dr. Vigilante has never been hired by the FDA to consult on any medical device.

[10] The list of non-exclusive factors include: (1) whether a theory has been tested; (2) whether it has been subject to peer review; (3) whether a technique has a potential rate of error, or standard operating procedures; and (4) whether a theory is generally accepted within the relevant scientific community. *Daubert*, 509 U.S. at 593-94.

(Vigilante 8/18/2016 Dep. at 74:10-13).[11] He has never been retained by a medical device manufacturer to provide consulting services. (*Id.* at 96:13-17). Despite offering numerous criticism of Medtronic's design process in evaluating human factors issues with respect to the Pump, Reservoir, and Infusion Set, he has never participated in design validation of a medical device under FDA regulations. (*Id.* at 96:18-21). He has never conducted a risk analysis for a medical device under FDA regulations, despite purporting to opine on this very topic. (*Id.* at 98:11-17). He has never been involved in a Corrective and Preventative Actions (CAPA) for a medical device. (*Id.* at 99:10-12). This lack of expertise is important, because Medtronic MiniMed's investigation into the potential for Temporary Blocked Vent when a user fails to follow the instructions was investigated and addressed as part of the CAPA process, pursuant to FDA regulations and requirements.

He has also never been involved in post-market surveillance program for a medical device, which evaluates trends in new and increased risks following the marketing of a medical device. (*Id.* at 99:17-20). He does not know what a design history file is for a medical device or what regulations govern it. (*Id.* at 105:16-106:10). The design history file is the FDA mandated regulatory file that includes all of the extensive design, development, verification, and validation documentation for a medical device, including the warnings and instructions for use. He has not read the federal regulations governing design, labeling and approval of medical devices or the international standard on medical device risk management (ISO 14971). (*Id.* at 107:8-108:10). He has never performed a risk analysis on a medical product. (*Id.* at 108:24-109:6). Furthermore, he has no opinions as to regulatory or FDA issues, and defers to other experts. (*Id.*

[11] A transcript of Dr. Vigilante's deposition, taken on August 18, 2016, is attached hereto as **Exhibit C**.

at 146:1-11; 147:3-9) (Vigilante 9/23/2016 Dep. at 410:8-12).[12]

He has never submitted labeling for a medical device pursuant to FDA regulations or ever been involved in the regulatory approval or clearance process of a medical device under either the PMA process or 510(k) process. (Vigilante 8/18/2016 Dep., at 98:11-99:5). Although the core of Dr. Vigilante's opinions attack the warnings and labeling of the Pump, Reservoir, and Infusion Set, remarkably he has never drafted a warning or label or instructions for a medical device. (*Id.* at 99:2-9). Furthermore, Dr. Vigilante is not an engineer and has no engineering experience. He is unqualified to testify regarding the design of the Pump, Reservoir, or Infusion Set, any alleged malfunction, or any alleged design defect.

Considering Dr. Vigilante's dearth of experience with medical devices and the FDA framework that governs them, it is unsurprising that he hardly reviewed or relied on any FDA materials in evaluating the Pump. He only cited to his single FDA resource as "support" for his vague proclamation about Medtronic's obligations as the designer of the product, (Vigilante Report at 9), and then again during a broad discussion attempting to define human factors as a science, (*id.* at 9-10). He did not even review the regulatory submissions to the FDA, or the FDA approval or clearance of the devices at issue.

Dr. Vigilante's human factors experience may extend to all manner of premises liability actions, auto accident cases, and even to the propriety of warnings in pharmaceutical advertising, but he presents nothing to suggest the needed expertise to evaluate an FDA regulated medical device. "[A] witness is not a qualified expert simply because he self-identifies as such." *Bradley*, 800 F.3d at 208-09. At best, his testimony would constitute speculation to the jury on how

[12] A transcript of Dr. Vigilante's deposition, taken on September 23, 2016, is attached hereto as **Exhibit D.**

general human factors analysis for everything from bicycle safety to pharmaceutical medication warnings applies to a type of product with which he has no experience. *Tamraz*, 620 F.3d at 671 ("'No matter how good' experts 'credentials' may be, they are 'not permitted to speculate.'" (quoting *Goebel*, 215 F.3d at 1088)). The remainder of Dr. Vigilante's extensive testimonial history contains only a single reference to the FDA in an unrelated context. Therefore, because of Dr. Vigilante's lack of expertise in this area, he is plainly not qualified to provide expert opinions related to the Pump and its components and should not be permitted to do so in this case. *See Ellipsis, Inc.*, 428 F. Supp. 2d at 758 (expert witness's "knowledge, skill, experience, training or education must be closely related to the subject matter of his testimony").

Lastly, Dr. Vigilante's report is ambiguous as to whether he intends to offer any engineering or design opinions, and is almost entirely focused on warnings. He references, without any support, that the pump "malfunctioned" and briefly describes the design of the P-Cap. To the extent he intends to offer any opinions on design, engineering, or whether there was a defect or malfunction in the device, he is also wholly unqualified to testify as to those engineering issues, given his lack of engineering experience and training, in addition to his lack of qualifications with respect to FDA regulated medical devices discussed above.

C. DR. VIGILANTE IS NOT QUALIFIED TO OFFER ANY OPINIONS ABOUT MEDICAL CAUSATION

Dr. Vigilante's findings twice state that that the alleged defects he identifies caused Ms. Brackin's injury and death:

> 5. Medtronic's failure to conduct an adequate human factors analysis was improper and unreasonably dangerous and created an unreasonably dangerous condition that caused or contributed to Pamela Brackin's injury and death.
> . . . .
> 9. Medtronic's failure to provide adequate instructions and warning was improper and unreasonably dangerous, rendering their Paradigm reservoir and infusion set

> defective and unreasonably dangerous, and caused Pamela Brackin's injury and death.

(Vigilante Report at 23-34). However, Dr. Vigilante has no medical training pertinent to Ms. Brackin's diabetes and no experience working as a medical professional. (*See generally* Vigilante's CV). As a Ph.D. in psychology and ergonomics, none of his educational background is indicative of any medical education. He has no medical degree or training whatsoever. Despite his voluminous testimonial history, he rarely discusses medical issues whatsoever, and on the rare occasions when the topic does arise, he (correctly) disclaims any medical expertise or ability to perform even a basic diagnosis. (Vigilante 3/10/2017 Dep. at 21:2-12).[13] Dr. Vigilante has disclaimed the ability or intent to offer medical testimony on the rare occasion when medical issues are raised during one of his depositions:

> Q. Understood. And Doctor, you are not a licensed physician?
> A. I am not.
> Q. Since you're not, do you feel that you would have the expertise to dispute a physician's medical diagnosis?
> A. Typically I don't get into diagnosis issues. I mean some of my background, I've got more training on anatomy and neurology than any physicians depending on their subspecialty but I don't do diagnosis.

(*Id*. at 21:2-12). Accordingly, any opinions offered by Dr. Vigilante on medical causation, including but not limited to the two statements identified above, lack a valid basis of expertise and should be excluded.

D. DR. VIGILANTE SHOULD BE PRECLUDED FROM OFFERING ANY OPINIONS OR TESTIFYING ABOUT ANY CAUSATION ISSUES BECAUSE HIS OPINIONS ARE BASED ON UNSUBSTANTIATED ASSUMPTIONS AND HE CANNOT TESTIFY WITH THE REQUISITE DEGREE OF CERTAINTY OR RELIABILITY

Dr. Vigilante's opinions as presented in his report are based on unsubstantiated

[13] A transcript of Dr. Vigilante's deposition, taken on March 10, 2017, is attached hereto as **Exhibit E.**

assumptions. *See McLean v. 988011 Ontario, Ltd.*, 224 F.3d 797, 801 (6th Cir. 2000) ("An expert's opinion, where based on assumed facts, must find some support for those assumptions in the record."). Throughout the report he begins by assuming the conclusions Plaintiff has hired him to reach. In the Introduction, Dr. Vigilante states: "At some point the system malfunctioned causing an unintended and unknown over-infusion of insulin into Pamela's body." (Vigilante Report at 2). Dr. Vigilante then wrote that the purpose of his investigation was to determine if:

> (1) "Medtronic's failure to conduct an adequate human factors analysis of its products was improper in a manner which caused or contributed to Pamela Brackin's injury and death."
>
> (2) "Medtronic provided adequate instructions and warning with its Paradigm reservoir and infusion set regarding the hazard associated with the potential blockage of the P-cap connector vent."
>
> (3) "Medtronic's failure to provide adequate instruction and warning regarding the hazard associated with the potential blockage of its P-cap connector vent was improper in a manner which caused or contributed to Pamela Brackin's injury and death."

This is not the approach of an objective, scientific analyst. Before any discussion of materials reviewed or steps taken, he has assumed a system malfunction, that the Medtronic Defendants failed to conduct an adequate human factors analysis, and that the Medtronic Defendants failed to provide adequate instruction and warning. In *Davison v. Cole Sewell Corp.*, 231 F. App'x 444, 449 (6th Cir. 2007), the Sixth Circuit held that an expert's causation opinion about an accident lacked a reliable foundation because the expert was unable to review poor photographs of the scene of the accident and instead assumed that a later viewing of the accident area "could have been similar" to that depicted in the photographs. Similarly, Dr. Vigilante has based all of his opinions on the assumption that Ms. Brackin received an unintended dose of insulin as a result of a system malfunction, discounting, without any apparent investigation, other potential causes.

(*See generally* Vigilante's Report). His subsequent opinions deal extensively with what he concludes was the cause of the assumed malfunction, but he makes no attempt to investigate whether Ms. Brackin in fact received an unintended dose of insulin or any cause of the unintended dose. He cites no testing or experimentation his report demonstrating a malfunction or temporary blocked vent actually occurred. His failure to investigate this critical link in the chain of causation is likely explained by the fact that, as discussed above, he does not possess the requisite medical expertise to determine if Ms. Brackin received an unintended dose of insulin and what could cause that unintended dose from an engineering perspective. Regardless, without this unsubstantiated assumption, nothing bridges the gap left between Dr. Vigilante's investigation and his ultimate findings.

The issue Dr. Vigilante tries to skirt with this description becomes clear when looking at the tortured chain of events required for him to arrive at his conclusion. From his report:

> (1) "***[I]f*** the reservoir is removed while the insulin vial is inverted, insulin ***can*** squirt out due to the increased pressure in the vial and contaminate the top of the reservoir";
> (2) "***If*** the top of the reservoir is contaminated with insulin from the transfer process, or any other liquid, it ***can*** get on the bottom/inner layer of the P-cap membrane";
> (3) "***If*** liquid gets on the bottom of the membrane, it ***can*** block the flow of air through the vents in the P-cap connector";
> (4) "***If*** the vents are blocked it ***can*** prevent the equalization of pressure within the reservoir to the atmospheric pressure";
> (5) "[T]he priming process ***can*** increase pressure in the reservoir"; and
> (6) "***If*** the P-cap membrane is contaminated with liquid and the vents are blocked, the increased pressure in the reservoir will not vent to the atmosphere and the plunger ***can*** begin to move on its own."

(Vigilante Report at 8-9 (emphasis added)). He concludes that this chain of events "***can*** lead to the unwanted delivery ***of an indeterminate quantity of insulin*** . . . ." (*Id.* at 9 (emphasis added)).

Dr. Vigilante's causation opinion requires no less than six distinct events, each of which *may or may not* lead to the possibility of a downstream event. And even at the end of this increasingly implausible set of assumptions, he is unable to state what quantity of insulin is likely to be delivered. Simply put, these findings all lack the degree of certainty required to support causation in this case. *See Lozar*, 529 F. App'x at 530 (quoting *Tamraz*, 620 F.3d at 675-76); *Newell Rubbermaid, Inc.*, 676 F.3d at 527 ("Red flags that caution against certifying an expert include reliance on anecdotal evidence, improper extrapolation, failure to consider other possible causes, lack of testing, and subjectivity . . . ."); *see also Davison*, 231 F. App'x at 449 (holding plaintiff's expert's "opinions are also legally insufficient because he failed to identify the cause of the alleged injury with a sufficient degree of certainty"). He has conducted no testing or experimentation to confirm there was in fact a temporary blocked vent or any malfunction, he simply assumes it took place. The testing performed by Medtronic MiniMed, Inc. demonstrated the Pump, the Infusion Set, and the Reservoir all functioned normally and there was no malfunction. Dr. Vigilante has not even reviewed these testing results. For these reasons, the Court should decline to allow Dr. Vigilante to present any opinions or testify, as his opinions lack the reliability needed to establish causation.

III. CONCLUSION

The foregoing memorandum of law demonstrates that none of Dr. Vigilante's expert opinions in this matter are admissible, and he should be precluded from testifying or otherwise presenting opinions at trial.

This 14th day of September, 2018.

Respectfully submitted,

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CERTIFICATE OF SERVICE

This is to certify that I have this day served a copy of the within and foregoing **DEFENDANTS MEDTRONIC, INC.'S AND MEDTRONIC MINIMED, INC.'S MEMORANDUM OF LAW IN SUPPORT OF MOTION TO EXCLUDE THE OPINIONS AND TESTIMONY OF WILLIAM J. VIGILANTE, JR., PH.D, CPE**, via ecf service and electronic mail all counsel of record as follows:

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